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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,429	04/02/1999	BRET A. SHIRLEY	5784-9	3707

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/285,429

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-34 is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-14 and 21-34 are pending.

Applicants' amendment (Paper No. 22) and formal drawings (Paper No. 23) filed August 12, 2002 are acknowledged, and applicant's response has been fully considered. Claims 1, 9 and 29 have been amended.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-14, 29 and 30 under 35 USC § 112, second paragraph, regarding the term "at least one pharmaceutically active agent", "a sufficient concentration", "at least one tonicifying agent", "such that" or "a biologically active variant thereof", is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 2-5 in Paper No. 22.

Claim Rejections - 35 USC § 102

3. The previous rejection of claims 1-8 and 13 under 35 USC § 102(b), as being anticipated by Sato *et al.* (U. S. Patent 4,605,555), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 6-7 in Paper No. 22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-3, 6-10, 13 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by Bontempo *et al.* (EP 0284249).

Bontempo *et al.* teach a lyophilized lymphokine composition for therapeutic administration comprises a pharmaceutical active agent, α -2 interferon (page 3, line 33), a succinate buffer (mixture of succinic acid and sodium succinate; page 4, lines 26-27) at 50 mM concentration (page 5, line 19), which is about 30 or 40 mM of succinate (claims 1, 2 and 3), an isotonic agent sodium chloride (page 4, lines 15-16; claims 9 and 10), a bulking agent, a stabilizer and a dispersant (Examples 1-4). The solution has a pH about 4.0 to about 8.0 (page 4, lines 20-22; claims 6-8 and 13), and is lyophilized (page 5, lines 2-10; claim 14).

In response, applicants indicate the specification teaches suitable concentration ranges include upper boundary of "less than about 50 mM, less than about 45 mM, less than about 40 mM, less than about 35 mM," (page 7, lines 25-27), and further assert if 50 mM was about "30 or 40 mM", applicants would not have recited 50 mM separately from 45, 40, 35 and 30 mM (pages 5-6 of the response). The argument is found not persuasive because the specification does not define the range for "about", thus, it is not clear what amount is as to "about 40 mM", is it 42, 45 or 50 mM? The recitation of 50 mM separately from 45, 40, 35 and 30 mM in the specification does not define the term "about", it merely indicate various preferred concentration ranges of succinate buffer, and the recited range for the upper boundary, for example, "less than about 40 mM" can be overlapped with "less than about 50 mM" since the term "about" is not specifically defined.

5. Claims 1-8, 13 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by Hwang-Felgner *et al.* (U. S. Patent 5,151,265).

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Hwang-Felgner *et al.* teach a liquid pharmaceutical composition comprises γ interferon (column 2, line 43), a succinate buffer (mixture of succinic acid and sodium succinate; column 3, lines 9-12) at concentration of succinic acid (0.27 mg/ml, 2.3 mM; column 3, line 61; Example 1) and disodium succinate (0.73 mg/ml, 4.5 mM; column 3, line 62; total succinate = $2.3 + 4.5 = 6.8$ mM), which is about 10 mM of succinate (claims 1-5). The solution has a pH about 4.0 to 6.0 (column 3, lines 3-5; claims 6-8), and the liquid formulation of γ interferon has a greater shelf life than the lyophilized formulation (column 4, line 9-column 5, line 10; Tables 1 and 2; claims 13 and 14).

In response, applicants indicate the specification teaches suitable concentration ranges include, for example, “about 7-70 mM, about 8-60 mM, about 9-50 mM, about 10-40 mM,” (page 7, lines 18-22), and further assert that based on the teachings of separate ranges, one of skill in the art would not reasonably conclude that a range having a lower boundary of “about 7 mM” is the same as a range having a lower boundary of “10 mM” (page 6 of the response). The argument is found not persuasive because the specification does not define the range for “about”, thus, it is not clear what amount is as to “about 10 mM”, is it 6, 7, 8 or 9 mM? The recitation of different concentration ranges does not define the term “about”, it merely indicate various concentration ranges of succinate buffer.

6. Claims 1-3 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Olefsky *et al.* (WO 96/40894).

Olefsky *et al.* teach a liquid pharmaceutical composition comprises protein kinase C antagonist, a succinate buffer at concentration of 0.05 M, which is about 30 or 40 mM of

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succinate (page 23, lines 5-15; claim 1-3), and the pharmaceutical carrier can be aqueous solution (claim 13).

In response, applicants present the same argument as indicated in the paragraph 4 (pages 7-8 of the response), the argument is not persuasive for the reason indicated in the same paragraph.

7. Claims 11 and 12 are rejected because they are dependent from a rejected claim.

Conclusion

8. Claims 1-14 are rejected. It appears claims 21-34 are free of prior art, thus are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

November 7, 2002

Karen Cochrane Carlson
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER